REMARKS

Reconsideration of this application in light of the above amendments and the following remarks is respectfully requested.

The Claim Amendments

Claims 1, 2 and 3 have been amended to expressly recite the essential characteristics of the microcatheters of this invention as "...having a degree of flexibility to traverse remote vascular locations and a degree of strength to withstand high pressure associated with catheter delivery of viscous liquid embolizing compositions..."

Support for this added wording may be formed, for example, in the Abstract.

Claim 26, directed to a kit of parts, has been amended to recite the presence of a driver to pressure the high viscosity liquid embolizing composition through the microcatheter. Support for this recitation of a driver unit may be found, for example in paragraph [0010].

Claim 24, which duplicated claim 23, has been canceled.

An improper claim dependency in claim 25 has been fixed as has a typographical error in claim 3.

The Present Invention

The present invention, may be embodied as a microcatheter, method of constructing a microcatheter or a kit of parts including a microcatheter. The invention is directed to the discovery that one can achieve a microcatheter with two conflicting properties – high pressure tolerance and high flexibility. The solution which this invention embodies calls for three distinct physical components to yield its beneficial properties:

1. an inner layer having a greater flexibility at the distal end than at the proximal end;

2. a braided wire layer having a higher pic rate and thus greater flexibility at the distal end than proximal end; and

3. an outer jacket having a greater flexibility at the distal end than at the proximal end (durometer selection).

Independent device claims 1, 2 and 3 each recite these three requirements.

The microcatheter of claims 1, 2 or 3 embodies these three components. Its extreme distal end flexibility permits it to traverse remote vascular locations. Its extreme proximal end strength permits it to withstand the high pressures associated with the delivery of high viscosity liquid embotic compositions. Claims 1, 2 and 3 have been amended to expressly recite these desired properties and characteristics.

Examples 2-7 illustrate the manufacture and testing of microcatheters of the invention and show their ten fold greater flexibility at their distal tip relative to the proximal end and high burst pressures of over 800 psi.

The Rejections

Claims 1-6 and 16 as last presented were rejected under 35 USC 102 (b) over Samson '978.

The Samson '978 patent is directed to a balloon-tipped braid reinforced catheter. It features an annulus for balloon inflation, a braid reinforced inner tubing assembly and a separate outer braid-reinforced tubing assembly.

The Office Action draws attention to several sections of Samson. The Abstract is noted. It is seen that the abstract mentions that the outer tubing assembly includes at least one polymer layer and a braid. The feature of the outer assembly noted here is its ability to provide kink resistance to the inner assembly.

Column 6, lines 15-25 is noted. This passage indicates that the distal end of the overall catheter (inner assembly plus outer assembly) can be more flexible (lower stiffness) than the proximal end.

Column 7, lines 30-50 is noted. This section refers to Figure 3 and its depiction of the outer assembly but does not discuss flexibility or burst resistance.

Column 3, lines 25-30 is noted. This section describes prior art which taught that varying "pick count" (AKA "pic count" herein) could be used to impart increased distal flexibility to a reinforced catheter.

It should be noted that at column 10, lines 24-39. Samson mentions that one can change stiffness by charging "pitch angle" of the braid. While, based on the teachings of the present application, this may be related to "pick count" or "pic count", Samson does not directly teach this. Thus it cannot be said that Samson, by itself, describes the variable pic rate braid called for in the present claims 1-6 and 16.

Samson discloses varying the composition of the outer coating of the outer tube assembly 230. (See column 8, line 66 through column 9, line 31.) Samson does suggest having an outer coating which is most flexible in the distal region as called for in the catheters of this invention.

However, it is not seen that Samson addresses improving flexibility of the cylindrical inner layer of its outer tube as a way of improving catheter performance.

This, in summary, while Samson does speak generally about having a catheter with increased flexibility at its distal end it does not teach the desirable combination of three separate but simultaneous features to impart such flexibility – that is –

the inner layer with varied flexibility;

the wire layer with varied pic rate;

the outer layer with higer proximal durometer (and hence lower flexibility at the proximal end).

Neither does this reference teach the advantage that such a structure permits intervention in remote vascular locations and the delivery of viscous materials thereto as now recited in claims 1-6 and 16.

It is further noted that claim 16 calls for a tapered overlayer as part of the outer layer. This feature is not seen in Samson.

Claims 23-25 were rejected under 35 USC 102 (b) over McGurk ‘659.

Claims 23 and 24 seem duplicative of one another so claim 24 has been canceled.

Claim 25 which depended improperly from claim 21 or 22 has now been amended to correctly depend from claim 23.

Claims 23 and 25 relate to a method of making the special high pressure-tolerant, high flexibility catheters of the type just described with reference to the Samson reference.

Claims 23 and 25 recite the presence of all three of the materials called for to provide the desired strength and flexibility – that is –

a liner being more flexible at its distal end than at its proximal end;

a wire braid having a higher pic rate at its distal end hence greater flexibility there; and

a multisegmented outer jacket having greater flexibility at its distal end.

The method involves shrinking the outer jacket segments over the two other components and fusing the multiple segments into a continuous outer jacket.

While McGurk does show the general process of fusing an inner liner, a braid and an outer coating on a mandrel, it does not teach the specific materials called for in claims 23 and 25 which lead to the desirable properties as described above.

Claims 7 and 8 were rejected under 35 USC 103 over Samson in view of Scribner '904. Claim 7 calls for an "about 8 wire" braid.

While Scribner does show an 8 wire braid (and for that matter Samson does too in the context of its braid-reinforced INNER tube assembly – see column 10, lines 20-25 of Samson) these teachings are not in the context of claim 7 with its special inner liner – outer layer and variable pic reinforcement – all designed to work together to give an especially flexible distal end – especially burst-resistant proximal end catheter.

Claims 9 and 10 were rejected under 35 USC 103 over Samson in view of Pray '987.

The Office Action correctly notes that these claims add recitations about pic rate which are not taught directly by Samson. Wile Pray may show variable pic rates and may suggest the general idea found in column 3 of Samson that increased pick rates provide increased flexibility, it still fails to provide a teaching of the underlying "3 factor" flexibility feature of the catheter of the present invention with its inner liner, braid-reinforcement and outer covering each increasing flexibility at the distal end and increasing burst resistance at the proximal end.

Claims 11, 12 and 13 were also rejected under 35 USC 103 over Samson in view of Pray. These three claims involve charging pic rate stepwire in the reinforcement braid. (Claim 10 involves continuous variation in pic rate.) The advantage to be had is the overall idea of charging pic rate. These are two ways to do this – stepwise and continuously.

Claims 10-13 seek to cover both of these ways of varying pic rate. It is not seen that an advantage of one over the other needs to be demonstrated in that the combination of these two references fails to suggest the overall catheter design now claimed.

Claims 14, 15, 17, 18 and 18 were also rejected over Samson plus McGurk.

Claims 14 and 15 call for the inner liner to be fluorocarbon or PTFE. The Office Action cites McGurk as teaching fluorocarbon and PTFE liner. (See also column 10, lines 40-55 of Samson for a possible teaching of such materials in Samson, itself.)

While these passages do mention these chemicals, they do not teach the variation in flexibility from proximal to distal end brought about by the three features called for in the claims from which claims 14 and 15 depend.

Similarly, claims 17, 18 and 19 describe certain chemical compositions for use in the outer layer but always in the context of the overall catheter with increased distal flexibility in all three of its components – liner, braid and other coating – a combination not taught in these two references.

Claims 20-22 were rejected under 35 USC 103 over Samson in view of Azam.

Claims 20-22 recite preferred durometer values for the most flexible regions of the outer jacket end, but always do so in the context of the overall catheter with its variable flexibility inner layer, braid and outer layer. While Azam does mention shore values for the distal end of its catheters similar to applicants that is not in the context of the present overall catheter so it cannot render these claims obvious.

Finally, claim 26 was rejected under 35 USC 103 over Evans '480 in view of Samson.

Claim 26 has been amended to specifically recite the presence of a drive unit to pressure the high viscosity embolizing composition through the microcather. This has been done to emphasize the ability of this catheter which makes up part of this kit to be flexible enough at its distal end to access remote vascular locations but strong enough at is proximal end to withstand high delivery pressures called for by the viscous embolizing liquids.

Evans certainly shows suitable embolizing compositions but does not do so in the context of the special catheter of the invention which makes up an essential part of the claimed kit. If one selected the catheter of Samson, one would not have the kit called for by claim 26 since the Samson catheter is not a "catheter of claim 1 or 2 or 3" as called for in claim 26.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

Date: September 5, 2006

By ______________________

William H. Benz
Attorney for Applicant
Registration No. 25,952

FOLEY & LARDNER LLP
Customer Number: 38706
Telephone: (650) 251-1124
Facsimile: (650) 856-3710